



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/467,100	12/10/99	COLEMAN	PF-0049-2-DI

INCYTE PHARMACEUTICALS INC
PATENT DEPARTMENT
3174 PORTER DRIVE
PALO ALTO CA 94304

HM22/0313

EXAMINER	
HUTSON, R	
ART UNIT	PAPER NUMBER

1652

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/467,100

Applicant(s)
Coleman et al.

Examiner
Richard Hutson

Group Art Unit
1652



☒ Responsive to communication(s) filed on Dec 27, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 5 and 14-29 is/are pending in the applicat

Of the above, claim(s) 5, 14-18, 21, and 26 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19, 20, 22-25, and 27-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1652

DETAILED ACTION

Election/Restriction

1. Applicants cancellation of claims 4, 6 and 7, amendment of claims 19, 22 and 23 and the addition of new claim 29 is acknowledged. Claims 5, 14-29 are at issue and are present for examination.

2. Applicants' arguments filed on 12/27/2000, paper No. 9, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicant's election with traverse of Group I, Claims 4, 6, 7, 19, 20, 22-25, 27 and 28 in Paper No. 9 is acknowledged. The traversal is as in Paper No. 6, on the ground(s) that the invention encompassed by the claims of group I could be examined at the same time as the invention encompassed by the claim of group VII. As was discussed in Paper No. 7, this is not found persuasive because while the searches for the groups overlap, they are not coextensive. The search for Group VII would require the search of subclasses unnecessary for the search of elected Group I. For example, search of Group I would require search of subclass 435/194 and search of Group VII would require search of subclass 435/6.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5, 14-18, 21 and 26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper Nos. 6 and 9.

Art Unit: 1652

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112: -

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 28 are indefinite in that it is unclear if the recitation "a polynucleotide complementary to a polynucleotide encoding the polypeptide comprising an amino acid sequence of SEQ ID NO: 2" refers to a polynucleotide that is the complement of the full length polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2, or if this also includes "complementary polynucleotides" that are not complementary to the full length of the polynucleotide that encodes SEQ ID NO: 2. This claim is interpreted broadly as being drawn to a method of using "complementary polynucleotides" that are not necessarily complementary to the full length polynucleotide that encodes SEQ ID NO: 2.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 19 (20 and 22 dependent from) is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant polynucleotide comprising a

Art Unit: 1652

promoter sequence operably linked to a polynucleotide encoding a polypeptide having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2, wherein said polypeptide has kinase activity, does not reasonably provide enablement for any recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide encoding a polypeptide comprising an amino acid sequence with 95% identity to an amino acid sequence of SEQ ID NO:

2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. The rejection is stated in the previous office action.

8. Applicants traverse this rejection on two different basis that is "How to use" and "How to make".

Applicants have been persuasive in there "How to Make" argument.

With respect to "How to use" applicants argue that the scope of the claim is fully enabled by the specification. Applicants amendment of claim 19 c) such that said fragment has kinase activity and applicants recitation at page 9, line 11 of Paper No: 9 that "the polypeptide fragments of Claim 19 have kinase activity", has overcome the rejection with respect to section c) of claim 19. With respect to claim 19, b), applicants further assert that a polynucleotide comprising "a naturally occurring amino acid sequence having at least 95% sequence identity to an amino acid sequence of SEQ ID NO: 2 over the entire length of SEQ ID NO: 2" encompasses polynucleotide variants encoding naturally occurring orthologs in related species, particularly human

Art Unit: 1652

polypeptide variants with mutations that result in altered activity. It is unclear what function a polypeptide variant with a mutation that results in “altered activity” has and absent a teaching of this “specific altered activity”, how the polynucleotides which encode these polypeptides are enabled with respect to their use.

9. Claim 19 (20 and 22 dependent from) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. The rejection is stated in the previous office action.

11. Applicants traverse this rejection on the basis that it was made for “naturally occurring sequence” and “fragments” separately.

In view of applicants amendment and argument with respect to claim 19 c) drawn to those recombinant polynucleotides comprising a promoter sequence operably linked to a polynucleotide encoding a polypeptide comprising a fragment of an amino acid sequence of SEQ ID NO: 2, wherein said fragment has kinase activity, applicants argument is persuasive.

With respect to claim 19 b) naturally-occurring sequence, applicants argue that the subject matter encompassed by the claims is either disclosed by the specification or is conventional or well known to one of ordinary skill in the art as the specification teaches the polypeptide of SEQ ID NO: 2, the specification describes where to find the claimed variants, gives the scope of the claims and tells how one can determine whether a given polypeptide

Art Unit: 1652

sequence falls within the scope of the claims. Applicants further assert that the specification teaches how to find polynucleotide variants which can be used to make polypeptide variants and therefore the distinguishing attributes of the naturally occurring polypeptides having at least 90% identity to the sequence of SEQ ID NO: 2 are fully described. However, it should be noted that the claimed genus of polypeptides of Claim 19, part b) are not fully described by the specification as each of this claimed genus includes polypeptides of a wide diversity of functions. This much larger genus of polypeptides includes species with a wide variety of functions and thus is not fully described by the specification. Furthermore, part b) recites a genus comprising all naturally-occurring amino acid sequences having 95% sequence identity to the sequence of SEQ ID NO: 2 over the entire length of SEQ ID NO: 2. This genus is at least so broad as to encompass all allelic variants of the polypeptide of SEQ ID NO: 1 (and might include all allelic variants of other genes if there are multiple highly homologous loci). Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

12. Claim 19, 20, 22-25 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

Art Unit: 1652

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly amended claims 19 and 22 and claim 29's recitation of "95% identity" is rejected as being new matter that is not supported by the original specification. Further, claims 19 (20 and 21 dependent from), 22, 23, (24 and 25 dependent from), 25 as previously added on 6/9/2000 in Paper No: 6, recite "90% sequence identity". This recitation is also not supported by the original specification.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 23-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvennoinen et al.

As discussed in the previous office action, Silvennoinen et al. teach the structure of the murine Jak2 protein-tyrosine kinase, its role in interleukin 3 signal transduction and the cloning of a full-length cDNA clone for murine Jak1 and Jak2 protein-tyrosine kinase. A comparison of the amino acid sequence of the murine Jak2 protein shows that its best local similarity is 93.3%

Art Unit: 1652

with that of SEQ ID NO: 2. Relative to SEQ ID NO: 1, the cDNA taught by Silvennoinen et al. has greater than 88 % best local similarity.

One of ordinary skill in the art at the time of filing would have been motivated to use the sequence taught by Silvennoinen et al. to design oligomers for use as primers to amplify and determine the level of mRNA encoding the murine Jak2 protein or to isolate other mRNAs encoding related proteins such as human Jak2 using hybridization or polymerase chain reaction methodology. As discussed above and in the previous office action, and seen in the comparison of the sequence of SEQ ID NO: 1 with the murine Jak2 cDNA, there exists many regions of identity between the two cDNAs. It is noted that it is a common practice in the art to design oligomers such that they do not correspond exactly to the sequence on which they are based. For instance often they are degenerate in order to identify additional members of a family and they incorporate additional bases for cloning, etc. Thus an oligomer of the polynucleotide comprising the nucleic acid sequence of SEQ ID NO: 1 is made obvious by Silvennoinen et al. Further, one of ordinary skill in the art would have been motivated to use these oligomers as part of a method for detecting the level of murine and human Jak2 mRNAs in tissue samples or identifying additional related mRNAs. Further motivation for the design and use of oligomers based on murine Jak2 is that Silvennoinen et al. teach that the Jak2 protein is regulated in response to IL-3 and is involved in signal transduction associated with hematopoiesis and there interest in the role of Jak1 and Jak2 genes in IL-3 signal transduction. Thus claims 23-25 and 27-29 are made obvious by Silvennoinen et al.

Art Unit: 1652

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 19, 20 and 22 are rejected under the judicially created doctrine of double patenting over claims 1-3 of U. S. Patent No. 5,914,393 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A purified polynucleotide consisting of a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 2.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Art Unit: 1652

Applicant traverses this rejection on the basis that the application which matured into U.S. Patent No: 5,914,393 from which this application is a divisional application was originally restricted to groups I (claims 1-5), group II (claims 1-3, 6 and 7) and group III (claims 1-3, and 8-10), of which applicants elected group II. Applicants therefore assert that 35 U.S.C. 121 prohibits a rejection of claims 19, 20 and 22 over U.S. Patent 5,914.393 under the judicially created doctrine of double patenting. This argument is not found persuasive in view of the following: The original restriction of application 08/567,508 grouped the linking claims 1-3 in each of groups I through III. Group III includes claims 1-3 and 8-10 indicating that these claims are in fact not patentably distinct from each other. As such the previous restriction requirement clearly set forth that claims such as current claims 19, 20 and 22 are not patentably distinct from the claims that issued. The previous restriction would prevent a rejection of claims 19, 20 and 22 over claims to oligomers compositions but the issued claims do not include this subject matter. Further section 804.1 of the M.P.E.P. lists a number of situations where the prohibition of double patenting rejections under 35 U.S.C. 121 does not apply. See especially, Section (B) which states the claims of the different applications or patents are not consonant with the restriction requirement made by the examiner, since the claims have been changed in material respects from the claims at the time the requirement was made. For example, the divisional application filed includes additional claims not consonant in scope to the original claims subject to restriction in the parent. Since the current claims are broader in scope than those of the original application

Art Unit: 1652

drawn to expression vectors host cells and methods of expressing the polynucleotide of claim 1, the rejection is maintained.

17. Claims 23-25 and 27-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U. S. Patent No. 5,914,393 . It is noted that in the previous rejection claim 26 was mistakenly included in the rejection even though this claim was not examined as was indicated in the response to applicants traversal and the office action summary sheet. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of detecting a polynucleotide comprising a sequence of SEQ ID NO: 1 or variants thereof (claims 23-25 and 27-29) is obvious over claims to the polynucleotide consisting of SEQ ID NO: 1 or the complement thereof (claims 1-3).

Applicants traverse this rejection on the basis that the appropriate rationale of obviousness was not provided in the previous office action for claims 23-28. Claims 23-25 and 27-29 drawn to methods of detecting a polynucleotide comprising a sequence of SEQ ID NO: 1 or variants thereof are obvious over claims to the polynucleotide consisting of SEQ ID NO: 1 or the complement thereof (claims 1-3), because one of ordinary skill in the art would be motivated to design PCR and hybridization probes based on the sequence of SEQ ID NO: 1 for use in methods of detecting the presence and level of polynucleotides encompassed by and related to SEQ ID NO: 1. The motivation for such methods is they would be useful for the characterization of these nucleic acid sequences and the role they play in natural physiology and/or disease such that this information could be used to treat or enhance these conditions.

Art Unit: 1652


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson Ph.D.
3/9/2001


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
/600